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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|---------------------------|---------------------|------------------|
| 09/965,697 | 09/27/2001 | Tarlochan Singh Dhadialla | A01115A (RH-0036) | 4412 |
| 37978 | 7590 | 11/13/2006 | EXAMINER | |
| RheoGene, Inc. 2650 Eisenhower Avenue Norristown, PA 19403 | | | BRANNOCK, MICHAEL T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1649 | |

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,697

Applicant(s)

DHADIALLA ET AL.

Examiner

Michael Brannock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 13 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4,9-12,14 and 15 is/are allowed.
- 6) ☒ Claim(s) 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 8/18/06/06, have been entered in full.

Claims 5 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant's election with traverse of Group I, claims 1-4, 9-12, and 16-20 in the paper filed 4/7/05 is acknowledged, as set forth previously. It is noted that claims 6-8 also read on the elected group and will thus be examined in this Office action, as set forth previously.

Response to Amendment

Applicant is notified that the rejections under 35 U.S.C. 102 and 103, as set forth in the prior office action, have been withdrawn in view of Applicant's amendments.

Maintained Rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the following reasons:

Claims 16 recites the step of "preparing a set of ligands, wherein each ligand is modified by stepwise pharmacophore element changes. This step renders the metes and bound

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unascertainable for the following reasons: the phrase “stepwise pharmacophore element changes” does not appear to be recognized in the literature and nor is this phrase used in the instant specification. An artisan would not know what limitations are placed on the claim by the presence of this phrase. It is unclear what is intended by a “step wise” i.e. a progressive movement of changes, there are no teachings regarding what is to be considered “step wise” and what are not, and there is no reference standard such that any progressive changes can be measured. Applicant argues that support for the phrase can be found at page 41. This argument has been fully considered but not deemed persuasive. As set forth above, there is no definition of nor use of this phrase in the specification.

Claim 16(f) requires identifying a subset of ligands from the screen of step d with diverse gene modulation properties, yet there is no step or steps that tell what or how ligands with “diverse gene modulation properties” are to be identified. No explanation is provided as to what constitutes “diverse gene modulation properties”. Additionally, as set forth previously, words such as “diverse” are relative words yet neither the specification nor the claims have provided a distinct teaching as to when the parameters of these words are exceeded, and thus the artisan could not be reasonably sure that he or she were practicing the claimed invention.

Applicant argues the terms used in the claims are given their ordinary English meanings. This argument has been fully considered but not deemed persuasive. Ordinary meanings of words that are relative and open ended, e.g. diverse, can render the metes and bounds of claim indefinite, as above.

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Additional reference of relevance: the following is considered relevant to the instant application but is not being relied upon as the basis of any objection or rejection.

Lafont R. et al., Journal of Insect Science, 3(7)1-30, 2003. The authors review the state of the art of ecdysteroid gene switch systems and state that the RHeoPlex systems have the possibility to regulate multiple genes in a coordinated manner, see 6 first paragraph, and, also to provided simultaneous, but independent regulation (i.e. orthogonal regulation), see last paragraph of page 7.

Allowable Subject Matter

Claims 1-4, 9-12, 14, 15 are allowed.

Conclusion

This application contains claims 5 and 13 drawn to an invention nonelected with traverse in Applicant's response of 4/7/2005. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX months.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



November 7, 2006



JANET L. ANDRES
SUPERVISORY PATENT EXAMINER